

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 8/7/2015

GAIN Report Number:

Kenya

Agricultural Biotechnology Annual

2015 Kenya Agricultural Biotechnology Report

Approved By:

Lee Schatz

Prepared By:

Carol N. Kamau

Report Highlights:

Bt corn and Bt cotton will likely be the first ever genetically modified crops to be cultivated in Kenya if the National Biosafety Authority (NBA) approves applications submitted for open field cultivation (environmental release). Submission of the first-ever open field cultivation applications is a major milestone for Kenya's agricultural biotechnology development, and a test of commitment to the existing regulatory framework. Genetically engineered (GE) products development has not previously moved beyond the confined field trials (CFT) stage.

The import ban on GE products remains.

Section I. Executive Summary:

On July 24, 2015, the Kenya Agricultural and Livestock Research Organization (KALRO) and the African Agricultural Technology Foundation (AATF) officially submitted to NBA an application for the open field cultivation (environmental release) of Bt corn in Kenya, developed under the Water Efficient Maize for Africa (WEMA) project. The WEMA Project is a public-private partnership that aims to improve corn yields by developing drought-tolerant and insect-pest protected corn hybrids. AATF scientists anticipate corn yields to increase by 20-35 percent above corn varieties developed in 2008.

Being a locally developed, royalty-free variety, local seed companies are expected to reasonably price the Bt corn seed.

NBA has opened a 30-day public comment period which ends on August 23, 2015 to discuss the food safety, environmental, socio-economic, and other concerns related to the application. If NBA approves the application, Bt corn will introduce cultivation of genetically modified crops in Kenya and the East African region. The next phases will be seed multiplication and commercialization.

Monsanto submitted their application to NBA for Bt cotton (Mon 15985) environmental release and market placement on August 4, 2015. NBA will screen the application for completeness before publishing it in the Kenya Gazette and in the mainstream newspapers. A 30-day public comment period will then commence.

CHAPTER 1: PLANT BIOTECHNOLOGY PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

Kenya has developed a significant capacity for agricultural biotechnology research and development. The following table presents genetically engineered (GE) crops under development in Kenya. Additional information on approved GE projects can be found at the website of the Kenyan National Biosafety Authority (NBA), the regulatory body that oversees biotechnology development in Kenya: Approved Genetically Modified Organisms Projects

| Crop | Trait | Institutions Involved | Stage of | Commercial | |
|------|-----------------|--|--------------------|--------------------|--|
| | | | Development | Release Date* | |
| Corn | Drought | KALRO ¹ , AATF ² , | Six Confined Field | 2018 | |
| | Tolerance / | CIMMYT ³ , and | Trials (CFTs) | | |
| | Water | Monsanto | completed at | | |
| | Efficiency | | KALRO Kiboko | | |
| | | | with good results. | | |
| | (Water | | | | |
| | Efficient Maize | | | | |
| | for Africa) | | | | |
| | Insect | KALRO, AATF, | Three seasons of | 2017 | |
| | Resistance | CIMMYT, and | CFTs completed at | Application for | |
| | | Monsanto | KALRO Kiboko | environmental | |
| | | | with excellent | release/open field | |
| | | | results. | cultivation | |
| | | | | submitted to NBA | |
| | | | | on July 24, 2015 | |

| | Drought Tolerance | Kenyatta University and ASARECA ⁴ | Contained use (greenhouse experiments) | 2030 |
|-----------------|--|---|---|--|
| Cotton | Insect resistance (bollworms) | KALRO and Monsanto | CFTs completed. | 2016/2017 Open field cultivation application submitted to NBA in August 4, 2015 |
| Cassava | Virus resistance | KALRO, Donald Danforth Plant Science Center; National Agricultural Research Organization, Uganda; National Root Crops Research Institute, Nigeria; International Institute for Tropical Agriculture (IITA). | One CFT season completed at Alupe, Busia | 2017 |
| | Biofortified with increased levels of iron, zinc, protein, vitamin A and vitamin E | Donald Danforth Plant Science Center, KALRO, IITA ⁵ and CIAT ⁶ | One CFT season completed at alupe, Busia for Vitamin A Biofortification. | 2018 |
| Sorghum | Biofortified with increased levels of iron, zinc, vitamin A and vitamin E | KALRO, AHBFI ⁷ , Dupont Business and Pioneer Hi-bred | Green house experiments concluded. CFT approved by NBA. | 2020 |
| Sweet Potato | Insect/weevil resistance | International Potato Center (CIP) and Kenyatta University | Laboratory and greenhouse transformation approved by NBA in April 2011 | 2020 |

Notes: ¹Kenya Agricultural and Livestock Research Organization; ²African Agricultural Technology Foundation; ³International Maize and Wheat Improvement Center; ⁴Association for Strengthening Agricultural Research in Eastern and Central Africa; ⁵International Institute of Tropical Agriculture; ⁶International Center for Tropical Agriculture; ⁷Africa Harvest Biotechnology Foundation International *FAS/Nairobi Estimates

Sources: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2014 Biotech Update

b. COMMERCIAL PRODUCTION

Kenya does not commercially produce GE crops or GE seeds.

c. EXPORTS

There is no commercial production of GE crops in Kenya and Kenya does not export GE crops to the United States or any other country.

d. IMPORTS

The Government of Kenya banned importation of GE foods on November 21, 2012. The move was prompted by the Ministry of Public Health. USDA/FAS Nairobi issued a full report titled Kenya Bans Imports of Genetically Modified Foods.

NBA is responsible for the approval process of import shipments of GE products. The authoritative legislation, Kenya's Biosafety Act of 2009, stipulates that the approval process should take 90-150 days. Also, the Kenya Plant Health Inspectorate Service (KEPHIS) requires imported GE plant products to have:

- A declaration from the country of origin that states the imports GE status, and
- A phytosanitary certificate.

Kenya is a net food importer of agricultural commodities, mainly corn, wheat, rice and edible oils.

e. FOOD AID RECIPIENT COUNTRIES

Kenya is a food aid recipient country. Some food aid commodities, like corn-soy blend, are GE products. Prior to the GE import ban, NBA approved imported GE corn-soy blend for humanitarian assistance through the World Food Program (WFP). Since the GE ban has come into effect, no humanitarian assistance containing GE products has been admitted. Details of past import approvals can be found on the NBA's Approved Genetically Modified Products for Imports and Transit website.

The GE import ban also affects food aid shipments destined for other countries. Under advisement of the US government, food aid destined for inland East African countries, which would ordinarily enter through the Port of Mombasa, is diverted to other ports.

PART B: POLICY

a. Regulatory Framework

The NBA, established by the Biosafety Act No.2 of 2009, is under the Ministry of Agriculture, Livestock and Fisheries. It is responsible for regulations and policies, as well as general supervision and control over the transfer, handling, and use of GE products. Four GE implementing regulations were released following the Biosafety Act 2009: Contained Use Regulation, 2011; Environmental Release Regulation, 2011; Import, Export, and Transit Regulation, 2011; and Labeling Regulation, 2012. Handling, Packaging, Storage, and Transportation of GE products was drafted by NBA in 2013 and is now under review.

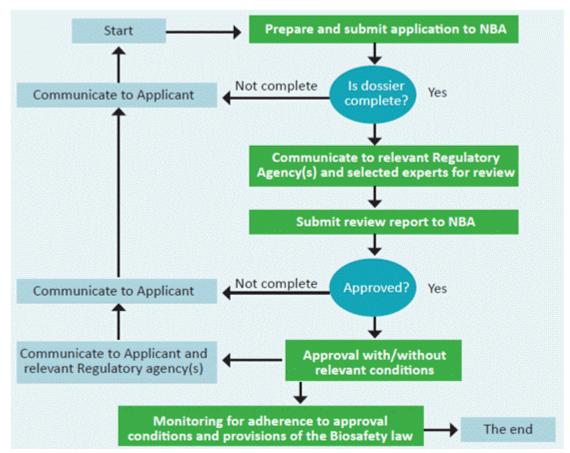
The NBA's board is comprised of representatives from eight other government regulatory agencies, listed below. Information on each agency's role in agriculture-biotechnology is available from their website:

• <u>Kenya Plant Health Inspectorate Service</u>, under the Ministry of Agriculture, Livestock and Fisheries, oversees the introduction, testing and use of biotechnology plants and seeds;

- <u>Department of Public Health</u>, under the Ministry of Health, safeguards consumers health through food safety and quality control, surveillance, prevention and control of food borne diseases;
- <u>Kenya Bureau of Standards</u>, (KEBS) under the Ministry of Industrialization and Enterprise Development, develops food standards, quality assurance, and testing;
- <u>National Environment Management Authority</u>, under the Ministry of Environment, Water, and Natural Resources, oversees environmental questions and conducts environmental impact assessments;
- <u>Pest Control Products Board</u>, under the Ministry of Agriculture, Livestock and Fisheries, regulates pesticide use;
- <u>Kenya Wildlife Service</u>, under the Ministry of Environment, Water, and Natural Resources, handles biodiversity and biotechnology related matters in wildlife and forestry;
- <u>Kenya Industrial Property Institute</u>, under the Ministry of Industrialization and Enterprise Development, handles intellectual property issues; and,

<u>Department of Veterinary Services</u>, under the Ministry of Agriculture, Livestock and Fisheries, protects and controls spread of animal diseases and pests to safeguard human health, improve animal welfare, and increase livestock productivity through production of high quality livestock and livestock products.

The following figure shows the process for approving production of GE crops developed in Kenya.



Source: NBA, 2012. As cited by ISAAA's "Status of Agricultural Biotechnology in Kenya, 2012" Handbook for Policy Makers.

b. Approvals

No plants are registered for cultivation, import and export in Kenya.

c. Field Testing

Kenya has allowed confined field trials (CFTs) for GE corn, cotton, cassava, sorghum, and sweet potato plants. The trials are conducted in selected KALRO stations on less than one acre. No GE trials are done in farmers' fields.

d. Stacked Events Approvals

CFTs of biofortified sorghum and cassava involve more than one modification (stacked events). NBA conducts risk assessment for each trait individually (per event) in order to approve a stacked product.

e. Additional Requirements

Not Applicable

f. Coexistence

Kenya does not have a policy on coexistence between GE and conventional crops. Once GE crops are released for commercialization, there will likely be challenges in managing coexistence with non-GE crops.

g. Labeling

The Kenyan government requires mandatory labeling of foods and feed containing at least one percent, by weight, of GE content. No labeling is required if the GE content is less than one percent of the total weight and the product has been approved by NBA as safe. For labeling regulation details visit: Labeling Regulations 2012 and 2012 Kenya Agricultural Biotechnology Report

h. Trade Barriers

In addition to the GE ban, mandatory labeling of GE foods effectively precludes importation of food with GE components. Violation of the mandatory labeling provisions imposes a fine up to \$230,000 and/or imprisonment up to ten years. The approval process for importation is also slow.

i. Intellectual Property Rights (IPR)

The Kenya Industrial Property Institute (KIPI) handles intellectual property issues that may pertain to genetic engineering, including patents, trademarks, utility models, industrial designs, and technovations.

j. Cartagena Protocol Ratification

Kenya was the first country to sign the Cartagena Protocol on Biosafety (CPB) on January 29, 2000. Kenya ratified the Protocol in 2002 and it entered into force on September 11, 2003. The international regulatory agreement requires countries to address environmental safety and human health by ensuring safe handling, transport, and use of GE products. NBA is Kenya's focal point of the CPB and shares data with the Biosafety Clearing House, a mechanism set by CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol.

k. International Treaties/Fora

Kenya is a member of several international organizations that deal with plant protection and plant health, including the International Plant Protection Convention (IPPC), the Codex Alimentarius (Codex), and the aforementioned CPB. Generally, these international frameworks seek to protect the environment and human health without unduly hindering international trade, aim to be transparent and in harmony with international trade regulations, and are science-based.

l. Related Issues

Kenya adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB on October 15, 2010. It gives Kenya flexibility to implement legislative, administrative or judicial rules and procedures relevant to liability and redress.

m. Monitoring and Testing

NBA is responsible for approving imports of GE products, while KEPHIS, KEBS, and Port Health (Department of Public Health) monitor and test agricultural commodity and food products imports at ports of entry. However, the Kenyan government has limited personnel and testing facilities for evaluating agricultural products for GE content.

n. Low Level Presence Policy

Kenya has no low level presence policy.

PART C: MARKETING a. Market acceptance

Studies conducted by CIMMYT, KALRO, and Kansas State University over five years revealed that Kenyan consumers are generally not aware of bioengineered foods. Processors and retailers showed a higher level of awareness, especially with regard to GE foods.

| Survey Group | Number Surveyed | Awareness (%) | | |
|----------------------------------|-----------------|---------------|----------|--|
| | | Biotechnology | GM Crops | |
| Urban consumers in Nairobi | 612 | 46 | 38 | |
| Rural consumers in Western Kenya | 121 | 16 | 13 | |
| Eastern Kenyans | 400 | 63 | 31 | |
| Gatekeepers at milling companies | 32 | 67 | 87 | |
| Supermarkets | 40 | 83 | 79 | |

Source: CIMMYT

b. Public/Private Opinions

Debate on biotech crops and bioengineered foods remains contentious and political. Some non-governmental organizations have exposed Kenyan consumers to negative messaging, while Kenyan agricultural research scientists and other non-governmental organizations continue to provide positive messaging.

c. Marketing Studies

Surveys and studies conducted in Kenya reveal that, although many respondents have heard about agricultural biotechnology, most are not informed about the science. Studies also indicate that most Kenyans wish to learn more about agricultural biotechnology, regardless of their current perceptions.

A 2011 study, conducted by Hannington Odame and Elijah Muange and sponsored by the UK's Department for International Development (DFID), asked Kenyan farmers and agro-dealers about GE seeds. The study was conducted in high-rainfall Uasin Gishu and low-rainfall Machakos. Among the results, summarized in the table below, they found that about 60 percent of respondents would buy GE seeds but wanted more information. More details are available in the report <u>Agro-Dealers and the Political Economy of Agricultural Biotechnology in Kenya</u>

| | Agree (% | <u>)</u> | | Don't Know | ow (%) | |
|-----------------------------------|----------------|----------|-------|----------------|----------|-------|
| Characteristic | Uasin Gishu | Machakos | Total | Uasin Gishu | Machakos | Total |
| Alleviate food shortage | 78.0 | 81.5 | 79.4 | 12.2 | 11.1 | 11.8 |
| More Nutritious | 12.2 | 38.5 | 22.4 | 34.1 | 34.6 | 34.3 |
| More Yield | 63.4 | 77.8 | 69.1 | 19.5 | 18.5 | 19.1 |
| Tolerate drought better | 43.9 | 70.4 | 54.4 | 34.1 | 22.2 | 29.4 |
| Resist pest better | 42.5 | 63.0 | 50.7 | 27.2 | 29.6 | 28.4 |
| Resist herbicide better | 19.5 | 48.1 | 30.9 | 39.0 | 40.7 | 39.7 |
| Contaminate local varieties | 51.2 | 42.3 | 47.8 | 17.1 | 30.8 | 22.4 |
| Dangerous to human health | 50.0 | 40.7 | 46.3 | 30.0 | 29.6 | 29.9 |
| Injurious to non-target organisms | 42.5 | 36.0 | 40.0 | 40.0 | 32.0 | 36.9 |

| More expensive | 53.7 | 75.0 | 61.5 | 17.1 | 20.8 | 18.5 |
|---------------------------|------|------|------|------|------|------|
| Require more expertise to | | | | | | |
| trade | 63.2 | 58.3 | 61.3 | 21.1 | 12.5 | 17.7 |
| Would trade in GM seeds | 48.8 | 75.0 | 57.4 | 26.8 | 25.0 | 26.2 |

Study conducted by Simon Chege Kimenju of the University of Nairobi and Hugo De Groote of CIMMYT, indicated that approximately 70 percent of Nairobi consumers would pay the same price for GE or non-GE corn meal. More details are available in the report <u>Consumers' Willingness to Pay for Genetically Modified foods in Kenya</u>.

PART D: CAPACITY BUILDING AND OUTREACH

a. Activities

The following U.S. Government, USDA-funded, and private-sector funded biotechnology capacity building and outreach activities have furthered agricultural biotechnology awareness, understanding, and appreciation in Kenya in the last two years.

- A Kenyan delegation that included nine Governors participated in a U.S. Agricultural Biotechnology Study tour organized by Crop Life International and Monsanto, March 1-9, 2014.
- Seven Members of Parliament drawn from the Parliamentary Committee on Agriculture, Livestock and Cooperatives visited the United States between November 30, 2013 and December 13, 2013 on a self-funded agricultural biotechnology study tour.
- Individual training on agricultural biotechnology through the Borlaug Fellowship program; five Kenyans will be trained in Biotechnology Policy and Communications in 2015 through the Cochran Fellowship Program.
- Agricultural biotechnology exposure tour to Brazil for policy makers and farmers.
- A KEBS staff member participated in the Biotechnology Regulation and Immersion Course for government regulators, held at the University of Missouri in collaboration with University of Ghent in Belgium, August 12-23, 2014.
- The Chairman of Kenya University Biotechnology Consortium (KUBICO) attended Biotech Boot Literacy camp in Davis, May 31-June 4, 2015.
- State Department to fund outreach activities to ISAAA and KUBICO for advancing public awareness on GE before the end of 2015 fiscal year.

b. Strategies and Needs

Top government leaders, cereal millers, traders, and agricultural research scientists widely acknowledge that modern biotechnology is an important tool for improving agricultural production in Kenya, and have continued to publicly support agricultural biotechnology. Agricultural biotechnology awareness campaigns initiated by institutions like BioAware, ISAAA, Open Forum on Agricultural Biotechnology, African Biotechnology Stakeholders Forum and Africa Harvest Biotech Foundation International avail credible information and demystify misconceptions related to agricultural biotechnology.

However, Department of Public Health's misguided perception and some non-governmental organizations opposed to the technology argue that more scientific data, particularity on safety to human, animals, and the environment, is needed before embracing the technology.

Kenya has advanced in agricultural biotechnology governance, as evidenced by the Biosafety Act of 2009, establishment of NBA, regulations and policies. To maximize on these gains, Kenya needs

encouragement to:

- Reverse the GE foods import ban;
- Commercialize Bt cotton;
- Continue public awareness on modern biotechnology and biosafety; and
- Continue capacity building on biotechnology to manage and strengthen research, development and trade.

CHAPTER 2: ANIMAL BIOTECHNOLOGY PART E: PRODUCTION AND TRADE

a. Biotechnology Product Development

International Livestock Research Institute (ILRI) scientists based in Nairobi, Kenya have plans to develop cattle that are resistant to Trypanosomiasis. Trypanosomiasis, also known as Nagana in cattle and sleeping sickness in humans, is a major problem to cattle keeping in Kenya (and the East African region), reportedly affecting over 70 percent of the reared cattle. The ILRI scientists have successfully developed a cloned Boran calf named "Tumaini" in the first phase of the project. In the second phase of the project, plans are underway to develop a new cloned Boran cow with a gene originating from baboons that will make it resistant to trypanosomiasis.

In addition, the ILRI and KALRO scientists are developing recombinant viral vaccines under contained use at the ILRI facility to control infections caused by members of the Mycoplasma mycoides cluster. Two trials are ongoing.

Livestock disease diagnostic test kits have also been developed and validated, awaiting commercial release. For example, latex agglutination test kit for CCPP (CAPRITESTR).

The key institutions involved in livestock biotechnology research and development include; International Livestock Research Institute, KALRO, and the Institute of Primate Research. NBA regulates application of biotechnology in livestock, and information on projects they have approved can be found in their website: Applications of Biotechnology in Livestock

b. Commercial Production

Not Applicable

c. Biotechnology Exports

Not Applicable

d. Biotechnology Imports

Not Applicable

PART F: POLICY

a. Regulation

The National Biosafety Act covers both plants and livestock, but no regulations have been developed specifically for animal biotechnology. However, NBA has developed protocols and guidelines on experiments under contained use for livestock research in animal biotechnology.

b. Labeling and Traceability

Not Applicable

c. Trade Barriers

Not Applicable

d. Intellectual Property Rights

Not Applicable

e. International Treaties/Fora

Not Applicable

PART G: MARKETING

a. Market acceptance

Not Applicable

b. Public/Private Opinions

Not Applicable

c. Market Studies

Not Applicable

PART H: CAPACITY BUILDING AND OUTREACH

a. Activities

No capacity building and outreach activities have been conducted in Kenya. However, New Technologies and Production Methods Division, Office of Agreements and Scientific Affairs - Foreign Agricultural Service/ USDA organized an Animal Biotechnology Regulatory Workshop held in Brasilia, Brazil August 18-22, 2014, where four Kenyans from the key regulatory agencies dealing with animals and animal products participated. Also included were two Ugandans and one Tanzanian.

• One NBA and one KALRO staff member will attend the Transgenic Animal Research Conference (TARC) in California, August 9-14, 2015, as a follow-up to the Brazil conference.

b. Strategies and Needs

The development of GE livestock production and regulations in Kenya would benefit from success in GE crop development and utilization.